

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Summary of Telephone Interview

Applicants wish to thank the Examiner for discussing the above-identified application with Applicants' representative. During the telephone discussions, the publication date of the cited Nitti reference was discussed. Applicants indicated that the reference does not indicate a publication date, and the Examiner agreed. Applicants also indicated that the publication date (of January 1, 2003) as indicated on the Information Disclosure Statement of December 10, 2008 was based upon the publication date provided in the Supplementary European Search Report, submitted with the same IDS. However, Applicants indicated that this publication date is improper (for reasons which will be provided in detail under the discussions of the obviousness rejections.)

The Examiner forwarded the Nitti reference to the U.S. PTO library, and requested the determination of a publication date. However, the U.S. PTO library was unable to ascertain a publication date for the reference.

Accordingly, the Examiner requested that Applicants provide a discussion regarding why the date of January 1, 2003 is incorrect. (Applicants have included the requested discussion in the response.)

The Examiner also requested that Applicants submit the requested information together with a Request for Continued Examination (RCE), since the submission of information regarding the publication date of the Nitti reference will require further consideration and/or search by the Examiner. The Examiner ensured Applicants that she would not issue a first action final rejection after consideration of the RCE.

Applicants appreciate the Examiner's willingness to discuss these matters in order to expedite the prosecution of this application.

Claim Amendments

Claims 1, 11 and 13 have been amended to remove the phrase “as the sole active ingredient”.

Claim 11 has been rewritten in independent form.

Claims 4, 8 and 9 have been cancelled, without prejudice or disclaimer.

Claims 17 to 20 are newly added. The subject matter of claim 17 is found at paragraphs 0060 to 0064 (Examples 1 to 4) of the present specification. The subject matter of claim 18 is found at paragraph 0065 (example 6) of the present specification. The subject matter of claim 19 is found at paragraphs 0060 to 0064 (Examples 1 to 4) of the present specification. The subject matter of claim 20 is found at paragraph 0065 (example 6) of the present specification.

Claims 21 and 22 are also newly added, and recite methods of use. The subject matter of claims 21 and 22 is found at paragraph 0014 (especially, page 9 lines 16 to 18) of the present specification.

Information Disclosure Statement

The Examiner is respectfully requested to consider the Information Disclosure Statement, filed concurrently herewith.

Claim of Priority

The Examiner has again failed to acknowledge the claim for foreign priority or receipt of the foreign priority document. The claim for foreign priority is set forth in the Declaration. Additionally, the Notice of Acceptance mailed May 17, 2006 indicates that the priority document was received by the PTO. Also, the Image File Wrapper for this application includes the certified copy of the foreign priority application.

Accordingly, the Examiner is respectfully requested to acknowledge the claim for foreign priority and receipt of the priority document with the next correspondence.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-9, 11 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is rendered moot by the claim amendments, discussed above.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Double Patenting Rejection

Claims 1, 4-9, 11 and 13 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending Application No. 11/815,499. Applicants kindly request that this rejection be held in abeyance until it is the only rejection remaining in the present application, at which point the rejection should be withdrawn.

Specifically, the present application has an effective filing date of August 3, 2004, while the '499 application has an effective filing date of February 2, 2006. Thus, the present application is the "earlier filed" of the two applications.

MPEP 804 (I)(B)(1) states, "If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

Thus, when the double patenting rejection is the only rejection remaining in the present application, it should be withdrawn, and the present application should be allowed to issue. Until that time, Applicants request that the rejection be held in abeyance.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 4-9 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Miyachi et al. (“Synthesis and Antimuscarinic Activity...”) in view of Nitti (“Transdermal Therapy for Overactive Bladder...”), and further in view of Versi et al. (US 2003/0191172) or Landau et al. (US 6,846,823).

Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Miyachi et al. in view of Nitti and either Versi et al. or Landau et al., as applied to claims 1, 4-9 and 11 above, and further in view of Luo et al. (US 6,586,000).

These rejections are respectfully traversed.

Initially, Applicants assert that the *alleged* publication date of the Nitti reference of January 1, 2003, as indicated on the IDS filed December 10, 2008, cannot be correct. The publication date set forth on the IDS was based upon the Supplementary European Search Report (also submitted with the same IDS) citing the Nitti reference. However, upon further consideration, the publication date of January 1, 2003 cannot be accurate, for the following reasons.

There is no specific indication of the publication date on the reference. Rather, the reference merely indicates “VOL. 5 SUPPL. 8 2003 Review in UROLOGY”. The cited article appeared in the *eighth supplement to the fifth volume* of 2003, which certainly would not have published on the first day of the year.

Please see Attachment 1, submitted herewith, which indicates that the eighth supplement to the fifth volume was released in December 2003.

Furthermore, Applicants have accessed the web site of “Reviews in UROLOGY”, and investigated when the site was updated (<http://www.archive.org/web/web.php>). According to the information obtained, it appears that the Nitti reference became available between December 7, 2003 and December 17, 2003. Specifically, the latest information recorded on the website on December 7, 2003 includes “Volume 5, Supplement 6”, and the latest information recorded on December 17, 2003 includes “Volume 5, Supplement 8”. (Please see Attachment 2, submitted herewith, which demonstrates the issues of Reviews in UROLOGY which were available on the website on December 7, 2003.)

For the reasons provided above, it is clear that the *alleged* publication date of January 1, 2003 is erroneous, and the publication date is likely between December 7, 2003 and December 17, 2003.

Furthermore, Applicants note that the priority date of the present application is August 4, 2003, which is prior to the publication date of the Nitti reference. Applicants enclose herewith a verified English translation of the priority application, thus perfecting the claim for foreign priority. Accordingly, the Nitti reference may no longer be cited as prior art against the present application. Since each of the obviousness rejections rely on the Nitti reference, the rejections have each been overcome for this reason alone. It is respectfully requested that the rejections be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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/Amy E. Schmid/

By 2011.02.25 11:48:20 -05'00'

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Attachments: (1) Cover and information page for Reviews in Urology, Vol. 5, Suppl. 8
(2) Screenshot from www.archive.org for Reviews in Urology on December 7, 2003.
(3) Verified English translation of priority application.